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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17/10/2002
C(2002) 4064

NOT FOR PUBLICATION

COMMISSION DECISION

of 17/10/2002

**amending Decision C(2001)818 on the marketing authorization for
the medicinal product for human use**

"TARGRETIN - bexarotene"

(Text with EEA relevance)

ONLY THE ENGLISH TEXT IS AUTHENTIC.

COMMISSION DECISION

of 17/10/2002

**amending Decision C(2001)818 on the marketing authorization for
the medicinal product for human use**

"TARGRETIN - bexarotene"

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products¹, as amended by Commission Regulation (EC) No 649/98²,

Having regard to Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93³, as amended by Commission Regulation (EC) No 1069/98⁴, and in particular Article 8(3) thereof,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products,

Whereas:

- (1) The medicinal product "TARGRETIN - bexarotene" entered in the Community register of medicinal products under No EU/1/01/178/001 authorised by Commission Decision C(2001)818 of 29 March 2001, as amended, complies with the requirements set out in Regulation (EEC) No 2309/93.
- (2) Ligand Pharmaceuticals UK Ltd submitted an application on 27 July 2001 pursuant to Article 6(1) set out in Regulation (EC) No 542/95.
- (3) The European Agency for the Evaluation of Medicinal Products delivered a favourable opinion formulated on 27 June 2002 by the Committee for Proprietary Medicinal Products,
- (4) Decision C(2001)818 should therefore be amended accordingly.

¹ OJ No L 214, 24. 8. 1993, p. 1.

² OJ L 88, 24.3.1998, p. 7.

³ OJ No L 55, 11.3.1995, p. 15

⁴ OJ L 153, 27.5.1998, p. 11

- (5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2001)818 is amended as follows:

1. Annex I is replaced by Annex I to this Decision;
2. Annex III B is replaced by Annex II to this Decision.

Article 2

This Decision is addressed to Ligand Pharmaceuticals UK Ltd, Innovis House, 108 High Street, Crawley, West Sussex RH10 1BB, UNITED KINGDOM.

Done at Brussels, 17/10/2002

For the Commission
Erkki LIIKANEN
Member of the Commission